DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride and Spectinomycin Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for oral use of lincomycin and spectinomycin soluble powder to make medicated drinking water for administration to chickens up to 7 days of age as an aid in the control of several bacterial respiratory diseases.

DATES: This rule is effective [insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; tel: 301–827–8549; e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–345 for Lincomycin-Spectinomycin (lincomycin hydrochloride monohydrate/spectinomycin dihydrochloride pentahydrate) Water Soluble Powder. The application provides for oral use of lincomycin and spectinomycin soluble powder to make medicated drinking water for administration to chickens up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae*

or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Phoenix Scientific's Lincomycin-Spectinomycin Water Soluble Powder is approved as a generic copy of Pharmacia & Upjohn's L-S 50 (lincomycin hydrochloride monohydrate/ spectinomycin sulfate tetrahydrate) Water Soluble Powder, approved under NADA 46 109. ANADA 200 345 is approved as of February 5, 2004, and the regulations are amended in part 520 (21 CFR part 520) by removing § 520.1263b and by adding § 520.1265 to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1263b [Removed and Reserved]

2. Section 520.1263b is removed and reserved.

3. Section 520.1265 is added to read as follows:

§ 520.1265 Lincomycin and spectinomycin soluble powder.

(a) *Specifications*. The following salts of lincomycin and spectinomycin are present in a soluble powder in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base:

(1) Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate.

(2) Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000009 for use of product described in paragraph (a)(1) of this section.

(2) No. 059130 for use of product described in paragraph (a)(2) of this section.

(c) *Tolerances*. See §§ 556.360 and 556.600 of this chapter.

(d) *Conditions of use in chickens*—(1) *Amount*. 2 grams of antibiotic activity per gallon of drinking water; administer as the sole source of water for the first 5 to 7 days of life.

(2) *Indications for use*. As an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

Dated: March 11, 2004.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

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